REMARKS

Applicants have cancelled claim 145 and have amended claim 166 to recite, "and wherein said fragment binds an antibody which binds to a polypeptide consisting of SEQ ID NO:4". This amendment is fully supported by the specification. See, for example, page 25, line 22 through page 26, line 15. Thus, no new matter has been added.

After entry of the above amendments, claims 141-144 and 146-172 are pending.

I. Rejections Under 35 U.S.C. §§ 101 and 112, First Paragraph

The Examiner rejects claims 141-172 under 35 U.S.C. §§ 101 and 112, first paragraph because the claimed invention is allegedly not supported by either a substantial asserted utility or a well established utility. The Examiner alleges that "the specification fails to assert if the claimed protein is over-expressed or under-expressed in any of the stated diseases." The Examiner further alleges that "the condition of perhaps being over expressed or perhaps being under-expressed does not provide for a specific, substantial assertion."

The Examiner acknowledges that the combination of references previously cited by Applicants "would corroborate the specification claims to a treatment or diagnosis of asthma" but only if "there was such an asserted utility". For example, the Examiner quotes the Applicant's specification on page 30, lines 14-18 wherein a specific and substantial assertion of utility is given:

> The ability of galectin 8, 9, 10, or 10SV to modulate growth regulatory activity may be therapeutically valuable in the treatment of clinical manifestations of such cell regulatory disorders. Disorders which can be treated include...asthma....

However, the Examiner states that the references would corroborate only an asserted "utility for the over-expression of SEQ ID NO:4 and the condition of asthma" (emphasis added). The Examiner then alleges that the specification does not provide this assertion because "it contemplates that the claimed polypeptides can be either over expressed or under-expressed in the condition of asthma" and that this disclosure is "tantamount to no assertion at all." Claims 141-172 are also rejected under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility under 35 U.S.C. § 101.

In response, Applicants respectfully disagree and traverse. The Examiner appears to be alleging that the asserted utility must not only be specific and substantial, but must also specifically disclose the mechanism of function underlying the assertion of utility. However, it is well established that an applicant is not required to set forth the mechanisms through which the invention functions, nor is the applicant required to even know how or why an invention works. *See e.g.*, Newman v. Quigg, 11 U.S.P.Q.2d 1340, 1345 (Fed. Cir. 1989); Diamond Rubber Co. v. Consolidated Rubber Tire Co., 220 U.S. 428, 435-36, 55 L. Ed. 527, 31 S. Ct. 444 (1911); Fromson v. Advance Offset Plate Inc., 720 F.2d 1565, 1570, 219 U.S.P.Q. (BNA) 1137, 1140 (Fed.Cir. 1983). Moreover, in Congoleum the Court stated, "It is clear that patentability is not barred by the failure of the inventors to understand the scientific principle or mechanism on which the claimed invention is based, so long as the method and operative result of the invention are correctly described." *See*, Congoleum Indus. v. Armstrong Cork Co., *339 F. Supp. 1036, 1057-1058 (1972).* The United States Court of Appeals for the Federal Circuit explicitly affirmed "[t]he PTO is not a guarantor of scientific theory and... it is not the province of the PTO to ascertain the scientific explanation." *See*, *In Re* Newman, 782 F.2d 971, 974 (1986). Accordingly, disclosure of a specific and substantial utility for the claimed polypeptides is provided in the specification on page 30, lines 14-18 as identified by the Examiner in the office action dated June 2, 2006. Such utility is supported by data in post filing date publications, which as acknowledged by the Examiner, "corroborate the specification claims to a treatment or diagnosis of asthma." Thus, the specific and substantial utility is also credible.

Applicants respectfully remind the Examiner that only one specific, substantial and credible assertion of utility need be made. Indeed, the M.P.E.P. at § 2107.02 states "[i]t is common and sensible for an applicant to identify several specific utilities for an invention...". Further, "[i]f applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established." *Id. See also In re Malachowski*, 189 U.S.P.Q. 432 (C.C.P.A. 1976); *Hoffman v. Klaus*, 9 U.S.P.Q.2d 1657 (Bd. Pat. App. & Inter. 1988). Additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. *See, e.g., Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown.") Thus, the Examiner's characterization of the specification's teaching of altered expression in asthma as

"tantamount to no assertion at all" is improper; the specification clearly asserts several utilities for the claimed polypeptides, and Applicants have shown that the invention meets at least one of the asserted objectives. Accordingly, Applicants respectfully assert that the rejection of the claims under 35 U.S.C. § 101 has been obviated, and should be reconsidered and withdrawn.

Further, the Federal Circuit has held that the utility requirement of 35 U.S.C. § 101 and the "how to use" requirement of 35 U.S.C. § 112, first paragraph, have the same basis, *i.e.*, the disclosure of a credible utility. *See In re Brana*, 51 F.3d 1560, 1564, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); *see also* M.P.E.P. § 2107(IV); Utility Examination Guidelines at 1098. As discussed above, the specification teaches more than one specific, substantial, and credible utility of the claimed invention, thereby enabling the skilled artisan to use the claimed polypeptides. Since the specification teaches more than one specific and immediate utility for the claimed invention, Applicants submit that the full scope of the claims is enabled. Accordingly, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

II. Rejection Under 35 U.S.C. § 112, First Paragraph - Enablement

The Examiner has rejected claims 166-172 under 35 U.S.C. § 112, first paragraph, alleging that the specification "fails to teach how to use said broadly claimed fragments of SEQ ID NO:4." The Examiner alleges, inter alia, that the art (Burch WO03/084467) recognizes "putative epitopes can be predicted using a computer to scan the sequence of a protein for amino acid sequences that contain a 'motif' or a defined pattern of amino acid residues associated with a particular MHC allele, but that the vast majority of these predicted epitopes fail to be immunogenic (page 5, lines 18-21)." The Examiner then asserts that specification does not teach how to use such alleged non-immunogenic fragments and thus undue experimentation would be necessary to use the broadly claimed fragments.

Applicants respectfully note that the reference relied upon by the Examiner is not prior art. In fact, the reference's publication date (October 16, 2003) is long after the filing date of the instant application (March 5, 1999). Additionally, the reference does not "provide evidence of what one skilled in the art would have known on or before the effective filing date of the patent application" and cannot be used to support an enablement rejection.

(M.P.E.P. § 2164.05(a)) Nevertheless, Applicants have amended claim 166 to recite, "and wherein said fragment binds an antibody which binds to a polypeptide consisting of SEQ ID NO:4". Applicants believe that this amendment addresses the Examiner's rejection and respectfully request that the instant rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

III. Double Patenting Rejections

The Examiner has rejected claim 145 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,468,768 and has rejected claims 145 and 149 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 of U.S. Patent No. 6,027,916.

With respect to the rejection of claim 145, Applicants have cancelled the claim, thereby obviating any rejection thereof. However, with respect to the rejection of claim 149, Applicants respectfully disagree and traverse as such a rejection is barred under 35 U.S.C. 121 due to the restriction requirement made in the parent application. 35 U.S.C. 121 provides, in part:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

As discussed in § 804.01 of the M.P.E.P., "[t]he third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a

reference against any divisional application, if the divisional application is filed before the issuance of the patent." Applicants respectfully direct the Examiner's attention to the Restriction Requirement issued on April 30, 1998 during the prosecution of U.S. Patent No. 6,027,916 (the parent of the instant divisional application), wherein a restriction was issued between claims directed to polypeptides (claims 9 and 12) and claims directed to polynucleotides (claims 1-11). It is further noted that claim 8 (directed to a method of producing peptides of the invention) was restricted as a claim drawn to a polynucleotide, while claim 9 (directed, inter alia, to an isolated protein encoded by the cDNA clone contained in ATCC Deposit No. 97733) was restricted as a claim drawn to a polypeptide.

Applicants note that currently pending claim 149 is drawn to polypeptides as evidenced by the restriction of claim 9 in the '912 patent, while claim 23 of U.S. Patent No. 6,027,916 recites a method of use of polynucleotides of the invention as evidenced by the restriction of claim 8 in the '912 patent. Because the corresponding claims were restricted into separate groups in a restriction requirement that was not withdrawn prior to issuance of the '912 patent, a rejection for obviousness-type double patenting is prohibited by 35 U.S.C. 121. Accordingly, the instant rejection should be reconsidered and withdrawn.

Conclusion

Entry of the above amendment is respectfully solicited. In view of the foregoing amendment and remarks, Applicants believe they have fully addressed the Examiner's concerns and that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

Should any additional fees be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an additional extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

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Respectfully submitted,

/Mark J. Hyman/

Mark J. Hyman
Registration No.: 46,789
HUMAN GENOME SCIENCES, INC.
Intellectual Property Dept.
14200 Shady Grove Road
Rockville, Maryland 20850
(240) 314-1224